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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,471	10/25/2001	Mehran M. Khodadoust	50200/002003	6131
21559	7590	09/10/2007		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER JOIKE, MICHELE K	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			09/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/029,471

Applicant(s)

KHODADOUST, MEHRAN M.

Examiner

Michele K. Joike, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 83-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 18, 2007 has been entered.

Claims 83-109 are pending and examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 83, 84 and 88-96 stand rejected under 35 U.S.C. 102(b) as being anticipated by Baetscher et al (U.S. 5,922,601). This rejection is maintained essentially for reasons made of record in the previous Office Action mailed May 15, 2006.

Response to Arguments Concerning Claim Rejections – 35 USC § 102 (b)

Applicant's arguments filed June 18, 2007 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Applicant claims constructs that require the selectable markers and the reporter gene to be integrated into the genome and under the control of an endogenous regulatory element in the host cell. In all of Baetscher's constructs, there is a promoter within the construct that drives expression of either reporter or the selectable marker. Baetscher never teaches a construct where all of the selection markers and reporter gene are under control of a host cellular promoter.

Applicant's arguments have not been found persuasive for the following reasons.

Applicant is focusing on the limitation of a cassette including a positive selection marker, a negative selection marker and a reporter gene integrated into the genome of at least one cell and responsive to one or more endogenous regulatory elements in at least one cell. Baetscher teaches integration of promoterless positive and negative selection markers (columns 4-6). Specifically, a vector containing promoterless markers, including positive and negative selection markers, is integrated into the genome of a cell. The markers are promoterless so that once integrated, they are under control of an endogenous regulatory element.

Claim Rejections - 35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 85 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Baetscher et al in view of MPEP § 2144.04 (VI)(C). This rejection is maintained essentially for reasons made of record in the previous Office Action mailed May 15, 2006.

Claims 87 and 106 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baetscher et al in view of Zambrowicz *et al.* (US 6,436,707; see entire document.) This rejection is maintained essentially for reasons made of record in the previous Office Action mailed May 15, 2006.

Claims 86, 97, 105 and 109 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baetscher et al in view of Massie et al. This rejection is maintained essentially for reasons made of record in the previous Office Action mailed May 15, 2006. As noted by Applicant, claims 98-104 and 107-108 were improperly included in the 102(b) rejection as the claims include the limitation of a transactivator. The claims should have been rejected with claims 86, 97, 105 and 109 that stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baetscher et al in view of Massie et al. Since there is some confusion, Examiner is reiterating the rejection, including claims 98-104 and 107-108.

Claims 86, 97-105 and 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baetscher et al in view of Massie et al. This is a new rejection necessitated by amendment.

Baetscher et al teach all of the elements set forth above. Briefly, Baetscher et al teach the construction of gene trap vectors comprising a splice acceptor site, positive/negative selection markers, IRES elements, Stop codons, polyadenylation sequences and reporter genes, in various orders. However, Baetscher et al do not teach a transactivator incorporated into a cassette or vector, specifically, they do not teach the transactivator being a tetracycline regulator (tTA).

Massie et al (J. of Virology, 72 (3): 2289-2296, 1998, specifically p. 2289, Materials & Methods and 2295) teach a cassette and then a vector comprising the tTA transactivator.

The ordinary skilled artisan, desiring to use a cassette or vector with a splice acceptor site, positive/negative selection markers, a reporter gene and a tTA transactivator, would have been motivated to combine the teachings of Baetscher et al teaching the construction of gene trap vectors comprising a splice acceptor site, positive/negative selection markers, IRES elements, Stop codons, polyadenylation sequences and reporter genes, in various orders, with the teachings of Massie et al, teaching a cassette and then a vector comprising the tTA transactivator, since a vector with tTA in it is useful for functional studies and gene therapy applications. It would have been obvious to one of ordinary skill in the art to incorporate tTA into the vector because the tTA system has been shown to be highly effective for the regulated expression of recombinant proteins. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered,

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absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)

Applicant's arguments filed June 18, 2007 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

1. Since Baetscher does not teach the limitation of a construct where all of the selection markers and reporter gene are under control of a host cellular promoter, and none of the secondary references remedy this fundamental deficiency, the obviousness rejections should be withdrawn.
2. In particular, Massie does not disclose a transactivator polypeptide that is integrated into the genome of a host cell and responsive to one or more endogenous regulatory elements in the cell.

Applicant's arguments have not been found persuasive for the following reasons.

1. Baetscher teaches a construct where all of the selection markers and reporter gene are under control of at least one host cellular promoter, therefore there is no deficiency to cure.
2. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871

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(CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Combined Baetscher and Massie teach a transactivator polypeptide that is integrated into the genome of a host cell and responsive to one or more endogenous regulatory elements in the cell.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nancy T. Vogel/
Primary Examiner, Art Unit 1636

Michele K Joike, Ph.D.
Examiner
Art Unit 1636